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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,987	12/26/2001	Guy Falardeau	PHARMA-87	7787
24999	7590	03/16/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, PC 2200 CLARENDON BLVD SUITE 1400 ARLINGTON, VA 22201			KIFLE, BRUCK	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,987

Applicant(s)

FALARDEAU ET AL.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31, 33 and 35 is/are rejected.
- 7) ☒ Claim(s) 32 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election of the species of compound #1 is acknowledged.

Improper Markush Rejection

Claims 1-31, 33 and 35 are rejected as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables X, Y, Z, W, Q, Q¹, T, T¹, B and n_Q are defined in such a way that they keep changing the core of the compound that determines the classification. By changing these values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula (I) does not have a significant structural feature that is shared by all of its alternatives which is inventive. Compounds embraced by formula (I) are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to the elected group would overcome this rejection.

Claim Rejections - 35 USC § 112

Claims 1-31, 33 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to the invention. The specification is not adequately enabling for the scope of the compounds claimed.

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Two compounds have been made which does NOT give a reasonable assurance that all, or substantially all of them, are useful. The claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of compounds.

There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." *Ex parte Lanham*, 108 USPQ at 135 states "It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful."

Also, see *In re Surrey* 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the instant anti-viral arts. Note in *Surrey*, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is enormous, in the billions of compounds, and therefore one compound within its scope is not remotely representative of such a scope. See MPEP 2164.03.

The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to

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be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Having established the breadth of the claims, *Wands* now requires that one consider the number of working examples presented in the instant specification. It is noted that there are only two examples in the instant specification. Therefore, one must consider the guidance provided by the instant specification and the prior art of record.

To practice the instant invention in a manner consistent with the breadth of the claims would require a substantial inventive contribution on the part of a practitioner which would involve the determination of the compounds which would inhibit viral replication in a mammal.

The situation with viruses may be contrasted with that for bacterial infections. Certain agents, especially tetracycline and β -lactams are routinely found effective against a broad range

of bacteria species. Thus, antibiotic activity against a single gram-positive species means that activity against all Gram-positive bacteria. The clinician uses this knowledge to prescribe a penicillin without determining which bacterium is responsible for the infection.

A far different situation prevails for viruses. Commonly a single antiviral agent will be effective against a single species but not effective against other viruses in the same genus. What few antiviral agents exist are effective against only a limited range of viruses. Amantadine has some effect on Influenza A but is ineffective against Influenza B or C. Foscavir is effective against HSV-1 and HSV-2 but ineffective against VZV. All three viruses are herpes viruses.

Applicants are referred to the first paragraph in the chapter titled "Antiviral Agents" in "Fields Virology, 3rd Ed." The approaches to viral treatment that have been fruitful take advantage of precisely defined molecular features of the virus and have recently resulted in effective therapy for herpes and AIDS. As is pointed out in the last paragraph of page 431 of "Fields Virology, 3rd Ed.": "The best targets for inhibition by antiviral are theoretically molecules serving a function unique to the virus". Viruses code for few enzymes that are vulnerable to chemical attack. Each virus tends to have its own set of enzyme systems. Viruses are classified on physical but not molecular features. It is optimistic in the extreme to believe that given the history of anti-viral research that an agent will be effective on such a diverse class of viruses that share physical but not molecular features.

Anti viral activity in mammals is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d

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833, 839, 166 USPQ 18, 24 (CCPA 1970). The breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error.

Allowable Subject Matter

Claims 32 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
March 12, 2004